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Citation: **1996 U.S. Dist. LEXIS 22739**

1996 U.S. Dist. LEXIS 22739, \*

ANTHONY LOPEZ and VELMA LOPEZ, Plaintiffs, v. WYETH-AYERST LABORATORIES, and DOES 1-20, inclusive, Defendants.

No. C 94-4054 CW

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

1996 U.S. Dist. LEXIS 22739

December 13, 1996, Decided  
December 13, 1996, Filed

**SUBSEQUENT HISTORY:** Affirmed, Lopez v. Wyeth-Ayerst Lab., 139 F.3d 905, 1998 U.S. App. LEXIS 11429 (9th Cir. Cal. 1998)

**DISPOSITION:** [\*1] Defendant's motion for summary judgment GRANTED. Action dismissed.

**CORE TERMS:** flu vaccine, causation, expert testimony, vaccine, scientific, moving party, animal, non-moving, prong, epidemiological, admissible, absence of evidence, summary judgment, non-swine, anecdotal, issue of causation, general population, tort law, scientifically, admissibility, neuritis, scientific evidence, warning, substantive law, material fact, peer review, pre-existing, evidentiary, reliability, regulations

**COUNSEL:** For ANTHONY LOPEZ, VELMA LOPEZ, Plaintiffs: Brian P. Evans, Brian P. Evans Law Offices, Walnut Creek, CA.

For WYETH-AYERST LABORATORIES, INC., defendant: Stuart M. Gordon, Gordon & Rees, San Francisco, CA.

For WYETH-AYERST LABORATORIES, INC., defendant: Hedy M. Powell, Wyeth-Ayerst Laboratories, Philadelphia, Pa.

For WYETH-AYERST LABORATORIES, INC., defendant: Charles L. Casteel, Davis Graham & Stubbs, Denver, CO.

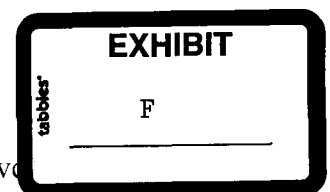
**JUDGES:** CLAUDIA WILKEN, UNITED STATES DISTRICT JUDGE.

**OPINIONBY:** CLAUDIA WILKEN

**OPINION:** ORDER GRANTING MOTION FOR SUMMARY JUDGMENT

Defendant Wyeth-Ayerst Laboratories ("Wyeth") moves for summary judgment with respect to Plaintiffs' product liability action on the grounds that there is no admissible, scientific evidence that Anthony Lopez's injuries were caused by Wyeth's product. Plaintiffs Anthony and Velma Lopez oppose this motion. The matter was heard on November 15, 1996. Having considered all of the papers filed by the parties and oral argument on the motion, the Court GRANTS the motion.

BACKGROUND



In this biological product liability action, Plaintiffs contend that the 1993-94 Formula Influenza [\*2] Virus Vaccine manufactured and distributed by Wyeth ("1993-94 Wyeth IVV"), a non-swine flu vaccine, caused Mr. Lopez to develop Guillain-Barre Syndrome ("GBS"). GBS is a neurologic condition that causes paralysis. While most GBS patients experience complete recovery, approximately 10 to 12% have some kind of permanent impairment.

On October 30, 1993, Mr. Lopez was administered the 1993-94 Wyeth IVV vaccine. He received no warning of any risks associated with the 1993-94 Wyeth IVV vaccine. He began to feel a tingling sensation in his hands and feet on November 3, 1993. On November 6th, 1993 he reported symptoms of weakness, numbness and tingling sensations to a doctor, and on November 7th, 1993, he was admitted to the emergency room with a diagnosis of GBS. GBS left him permanently paralyzed below his knees.

Plaintiffs proffer the expert testimony of Drs. Peter Lichtenfeld and William Patrick Joseph to show a causal link between the flu vaccine and Mr. Lopez's GBS. Dr. Joseph stated that he had not performed any studies regarding the association between a flu vaccine and GBS.

#### STANDARD OF REVIEW

Summary judgment is properly granted when no genuine and disputed issues of material [\*3] fact remain, and when, viewing the evidence most favorably to the non-moving party, the movant is clearly entitled to prevail as a matter of law. Fed. R. Civ. P. 56; Celotex Corp. v. Catrett, 477 U.S. 317, 322-23, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986); Eisenberg v. Insurance Co. of North America, 815 F.2d 1285, 1288-89 (9th Cir. 1987).

The moving party bears the burden of showing that there is no material factual dispute. Therefore, the Court must regard as true the opposing party's evidence, if supported by affidavits or other evidentiary material. Celotex, 477 U.S. at 324; Eisenberg, 815 F.2d at 1289. The Court must draw all reasonable inferences in favor of the party against whom summary judgment is sought. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587, 89 L. Ed. 2d 538, 106 S. Ct. 1348 (1986); Intel Corp. v. Hartford Accident and Indem. Co., 952 F.2d 1551, 1558 (9th Cir. 1991).

Material facts which would preclude entry of summary judgment are those which, under applicable substantive law, may affect the outcome of the case. The substantive law will identify [\*4] which facts are material. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986).

Where the moving party does not bear the burden of proof on an issue at trial, the moving party may discharge its burden of showing that no genuine issue of material fact remains by demonstrating that "there is an absence of evidence to support the non-moving party's case." Celotex, 477 U.S. at 325. The moving party is not required to produce evidence showing the absence of a material fact on such issues, nor must the moving party support its motion with evidence negating the non-moving party's claim. Id.; Lujan v. National Wildlife Federation, 497 U.S. 871, 885, 111 L. Ed. 2d 695, 110 S. Ct. 3177 (1990); see also Bhan v. NME Hospitals, Inc., 929 F.2d 1404, 1409 (9th Cir. 1991), cert. denied, 502 U.S. 994, 116 L. Ed. 2d 639, 112 S. Ct. 617 (1991). If the moving party shows an absence of evidence to support the non-moving party's case, the burden then shifts to the opposing party to produce "specific evidence, through affidavits or admissible discovery material, to show that the dispute [\*5] exists." Bhan, 929 F.2d at 1409. A complete failure of proof concerning an essential element of the non-moving party's case necessarily renders all other facts immaterial. Celotex, 477 U.S. at 323.

#### DISCUSSION

In order to establish causation for their claims, Plaintiffs must present admissible evidence that (1) the 1993-94 Wyeth IVV vaccine can cause GBS (general causation), and (2) that it did in fact cause Mr. Lopez's GBS (specific causation). *Casey v. Ohio Medical Products*, 877 F. Supp. 1380, 1382 (N.D. Cal. 1995); see also *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1320 (9th Cir. 1995), cert. denied 516 U.S. 869, 116 S. Ct. 189, 133 L. Ed. 2d 126 (1995) ("Daubert II") (under California tort law, plaintiffs must prove that their injuries were the result of the accused cause and not some independent factor).

Wyeth contends that there is an absence of evidence to support to support Plaintiffs' case on the issue of causation. According to Wyeth, Plaintiffs have no scientifically valid evidence to establish that the 1993-94 Wyeth IVV vaccine can cause GBS, in general, [\*6] or that it did cause Mr. Lopez's GBS. Specifically, Wyeth alleges that Plaintiffs' experts' opinions are not admissible under Federal Rule of Evidence 702 because they neither meet the "scientific knowledge" prong nor the helpfulness prong of the test for admissibility of expert testimony as set out in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 591-92, 125 L. Ed. 2d 469, 113 S. Ct. 2786 (1993) ("Daubert I").

Plaintiffs argue that because their expert opinions meet the Daubert I requirements, they are admissible, and that they establish the causation element of their prima facie case.

#### A. Admissibility of Expert Scientific Testimony

In determining the admissibility of expert scientific testimony under Federal Rule of Evidence 702, the Court must engage in a two part analysis: (1) to determine reliability, the Court must decide whether the expert testimony reflects or pertains to scientific knowledge; and (2) to determine relevance, the Court decide whether the expert testimony logically advances a material aspect of the proposing party's case. *Daubert II*, 43 F.3d at 1315 (citing *Daubert I*, 509 U.S. at 589-96); [\*7] see also *Lust v. Merrell Dow Pharmaceuticals, Inc.*, 89 F.3d 594, 597 (9th Cir. 1996).

##### 1. Basis in scientific knowledge

To determine whether the expert testimony is based on scientific knowledge, the Court may consider the following factors: "whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it's been subjected to peer review and publication; whether it can be and has been tested; and whether the known or potential rate of error is acceptable." *Daubert* 43 F.3d at 1316 (citing *Daubert I*, 509 U.S. at 592-94). These factors are merely illustrative, not exhaustive nor definitive. *Daubert* 43 F.3d at 1316-17. The focus of this inquiry "is not on the correctness of the expert's conclusions, but on the soundness of his methodology." *Id.* at 1318.

Another factor is whether the opinions were based on pre-existing independent research, or were expressly formed for the purposes of testifying. *Id.* at 1317. In this case, Plaintiffs' experts' opinions are not based on their own, pre-existing, independent research. Where the expert testimony is not based on independent research, the party offering it "must [\*8] come forward with other objective, verifiable evidence that the testimony is based on 'scientifically valid principles'", such as peer-reviewed publications. *Id.* at 1317-18. Alternatively, the experts must explain precisely how they went about reaching their conclusions and point to some objective source to show that they have followed the scientific method. *Id.* at 1319.

In this case, Plaintiffs' expert Dr. Lichtenfeld relies on the following as the basis for his opinion: the fact that an influenza vaccine is one of the recognized antecedent events to the onset of GBS; the fact that Mr. Lopez's medical records showed no other precursor event; a number of anecdotal reports in the medical literature of neurologic reaction to the flu

vaccine; two animal studies; and case reports. Plaintiffs' other expert, Dr. Joseph, relies on similar information.

Plaintiffs also say that their experts are relying on epidemiological studies. However, they do not cite any studies, other than swine-flu vaccine studies, to support their opinions. Rather, they seem to argue that epidemiological studies are not very helpful in addressing the causes of GBS because of problems with reporting. They [\*9] cite no authority to support this proposition.

Finally, Plaintiffs say that their experts are relying on Wyeth's product literature, which lists GBS under "adverse reactions," n1 testimony from a Wyeth employee that there is a temporal association between a flu vaccine and GBS, and a 1977 "Dear Doctor" letter than cautioned about the possible association between a flu vaccine and GBS. The Court understands that this evidence tends to show that there is a wide recognition of a possible relationship between a flu vaccine and GBS.

----- Footnotes -----

n1 Plaintiffs argue that this adverse reaction warning has strong evidentiary significance because, pursuant to FDA regulations, such warnings are required as soon as there is significant medical evidence of a possible health hazard. 21 C.F.R. § 201.57(e). However, the FDA regulations also state that "a causal relationship need not have been proved" before such a label is required.

----- End Footnotes-----

For the reasons set forth below, the Court is not convinced that this evidence [\*10] is sufficient to form a scientifically valid basis for the doctors' opinions under the Daubert I standard.

In essence, Plaintiffs' experts' opinions are based on the fact that the medical community recognizes that there is a possible relationship between a flu vaccine and GBS, that Mr. Lopez had a flu vaccine a short time prior to the onset of GBS, and that Mr. Lopez's medical history does not show any other precursor events. The experts offer no theory to explain how, from this information, they were able to eliminate all other potential causes of GBS.

This is particularly troubling in light of Dr. Joseph's statement that 30 to 40% of the GBS cases have idiopathic or unknown causes, and Wyeth's expert's uncontroverted testimony that there has been no epidemiological study showing increased incidence of GBS in persons receiving a non-swine flu vaccine, such as the 93-94 Wyeth IVV, as compared with persons in the general population. In fact, the epidemiological studies that are available, including one large study using data from U.S. military personnel, have shown that the occurrence of GBS among non-swine flu virus vaccinees did not exceed the expected background rates in the [\*11] general population. Epidemiological evidence is one of the most valuable pieces of scientific evidence of causation. Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307, 311 (5th Cir. 1989), modified 884 F.2d 166 (5th Cir. 1989), cert. denied 494 U.S. 1046 (1990); Casey v. Ohio Medical Products, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995) (considering lack of epidemiology study an important factor in determining reliability).

In Daubert II, the Ninth Circuit found the expert testimony based on similar grounds unreliable because the expert failed to offer a theory to explain how he was able to eliminate all other potential causes of the alleged injury. Daubert II, 43 F.3d at 1319.

Additionally, the Court finds other aspects of the experts' opinions troubling. With respect to

the anecdotal or case reports, Dr. Lichtenfeld states that there are reports concerning patients who have received a flu vaccine, and who have then developed GBS. However, he does not state whether these anecdotal reports isolate and exclude other potential causes of GBS. Generally, courts have excluded expert causation [\*12] testimony that is based upon such anecdotal or case reports. See, e.g., *Casey v. Ohio Medical Products*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995) ("Such case reports are not reliable scientific evidence of causation, because they simply describe reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a control group; do not isolate and exclude potentially alternative causes; and do not investigate or explain the mechanism of causation.")

With respect to the animal studies, Dr. Lichtenfeld states that the studies show that a flu vaccine was capable of inducing or contributing to allergic neuritis, which is an animal equivalent of GBS. While at least one of the studies has been subject to peer review, Dr. Lichtenfeld does not explain how these studies show that a flu vaccine is capable of causing GBS in humans, or the basis for his conclusion that the studies demonstrate causation in humans. An expert's mere citation to animal studies, without more, is not enough to show that the expert's opinion is based upon scientific knowledge. See *Daubert II*, 43 F.3d at 1319.

For example, Plaintiffs rely upon [\*13] a copy of a confidential draft of an animal study entitled "Experimental Antigen-Induced Neuritis [EAIN] - a Possible Model for Guillian-Barre Syndrome," in which the author writes, "Wyeth might find the EAIN model of future use to predict which strains of influenza might give vaccine complications such as GBS. It might also be used to determine which components of the vaccine cause the disease and to eliminate them or modify them."

However, Wyeth's expert explains that this model is distinguishable because it requires an adjuvant, and because animal studies with the vaccine and no adjuvant have not produced experimental neuritis. Plaintiffs do not address these issues.

## 2. Relevancy of Proffered Expert Testimony

Even if the proffered expert testimony were found to be sufficiently reliable, it must still satisfy the second prong of *Daubert I*. The second prong requires "a valid scientific connection to the pertinent inquiry as a precondition to admissibility." *Daubert I*, 509 U.S. at 592. In this case the pertinent inquiry concerns the issue of causation.

In assessing whether the proffered expert testimony will assist the trier of fact in resolving this [\*14] issue, the Court must look to the governing substantive standard, which in this case is supplied by California tort law. *Daubert II*, 43 F.3d at 1320. Under California tort law, Plaintiffs must prove that their injuries were, more likely than not, the result of the accused cause and not some independent factor. *Id.*

In this case, Plaintiffs have not made the requisite showing of relevance. Even if they have established that some flu vaccine is capable of causing GBS, they have not established that the 93-94 Wyeth IVV, the flu vaccine at issue in this case, is capable of causing GBS. Nor have they established that there is any significant, increased incidence rate of GBS in persons receiving a non-swine flu vaccine, such as the Wyeth IVV, above the normal population. In short, they have not met the relevancy standard required by *Daubert I*.

Because the proffered testimony does not satisfy either prong of the *Daubert I* test, it is not admissible. Without this testimony, there is an absence of evidence to support Plaintiffs' case on the issue of causation, and Wyeth must prevail.

## CONCLUSION



For the foregoing reasons, Defendant's motion is GRANTED.

IT IS [\*15] SO ORDERED.

Dated: DEC 13 1996

CLAUDIA WILKEN

UNITED STATES DISTRICT JUDGE

JUDGMENT - ENTERED IN CIVIL DOCKET DEC 17 1996

This action came on for hearing before the Court, the Honorable Claudia Wilken, United States District Judge, presiding, and the issues having been duly heard and the Court having duly rendered its decision as set forth in its Order Granting Motion for Summary Judgment filed December 13, 1996,

IT IS HEREBY ORDERED AND ADJUDGED:

That Plaintiffs Anthony Lopez and Velma Lopez take nothing, that the action be dismissed on the merits, and that Defendant Wyeth-Ayerst Laboratories recover of Plaintiffs its costs of action.

Dated: DEC 13 1996

CLAUDIA WILKEN

UNITED STATES DISTRICT JUDGE

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Citation: **1998 U.S. App. LEXIS 11429**

*139 F.3d 905; 1998 U.S. App. LEXIS 11429, \**

ANTHONY LOPEZ and VELMA LOPEZ, Plaintiffs-Appellants, v. WYETH-AYERST  
LABORATORIES, INC., a Delaware corporation, Defendant-Appellee.

C.A. No. 97-15143

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

139 F.3d 905; 1998 U.S. App. LEXIS 11429

February 13, 1998, Argued and Submitted, San Francisco, California  
February 25, 1998, Filed

**NOTICE: [\*1]** DECISION WITHOUT PUBLISHED OPINION

**PRIOR HISTORY:** Appeal from the United States District Court for the Northern District of California. D.C. No. CV-94-04054-CW. Claudia Wilken, District Judge, Presiding.

Reported in Full-Text Format at: 1998 U.S. App. LEXIS 3146.

**OPINION:** AFFIRMED.

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